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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,592	08/15/2005	Morten Sloth Weidner	030307-0249	1815

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,592	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/2/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64,66,67,69-76 and 81-96* is/are pending in the application.

4a) Of the above claim(s) *79 and 81-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64, 66-67, 69-76, and 93-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 1/2/2009. Claims 64, 71, and 79 have been amended. Claims 1-63, 65, 68, 77-78, and 80 are cancelled. Claims 93-96 are newly added. Claims 79 and 81-92 remain withdrawn as pertaining to the non-elected invention. Thus, claims 64, 66-67, 69-76, 79, and 81-96 are pending and claims 64, 66-67, 69-76, and 93-96 are currently under consideration.

WITHDRAWN REJECTIONS

1. In view of Applicant's amendment to claim 71, the rejection of claim 71 under 35 U.S.C. 112, second paragraph, as being indefinite is herein withdrawn.

Response to Arguments

2. Applicant's arguments filed 1/2/2009 have been fully considered but they are not persuasive.

The Applicant argues that Shalita teaches away from combining nicotinamide together with an active agent that displays antimicrobial action, such as 1-glyceryl monocaprylate, because antimicrobials are associated with resistant microorganisms such as Propionibacterium. The Examiner respectfully disagrees. Shalita et al. do not teach 1-glyceryl monocaprylate in particular is associated with resistant strains of microorganisms. The antibiotic resistance referred to by Shalita et al. has only been demonstrated by the antibiotics erythromycin, clindamycin, tetracycline, trimethorprim, and doxycycline (see Eady et al., "Antibiotic-resistant propionibacteria in acne: need for

policies to modify antibiotic usage" *BMJ*, 1993; 306: pgs 555-556). Further, as recognized by Shalita et al, the mechanism of action of nicotinamide in treating acne is unknown and Traupe et al. clearly teach 1-glyceryl monocaprylate for the treatment of acne, particularly wherein the acne is cause by Propionibacterium (see column 4, les 29-36; claims 4-5). Moreover, it would be expected that the combination of nicotinamide with 1-glyceryl monocaprylate would exhibit at least an additive effect in treating acne. Thus, any alleged side effects from the 1-glyceryl monocaprylate could be minimized by using a lower dosage of 1-glyceryl monocaprylate while still achieving the same acne treating effect.

Applicants further alleges that a "combination of fatty acid esters of polyhydroxanes and pyridine carboxy derivat[ives] is unexpectedly effective in suppressing hypersensitivity and inflammation reactions." It appears the Applicant is alleging the combination of nicotinamide with 1-glyceryl monocaprylate have a synergistic effect in suppressing hypersensitivity and inflammation reactions (i.e. unexpected results).

In response it is respectfully submitted that it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably

commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the "evidence" of alleged synergism is not commensurate with the breadth of the claims. Only two specific formulations are provided as evidence: 1-glyceryl monocaprylate and nicotinamide in a molar ratio of 1:14 and in a molar ratio of 2:7 (see Examples 111 and 112), which does not provide sufficient evidence that the remaining composition formulations possible under the claim scope would exhibit the same or similar unexpected results. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

Thus, for these reasons, Applicant's arguments are found unpersuasive. The instant claims are still considered properly rejected under 35 USC 103(a), and said rejection is maintained.

REJECTIONS

3. The following rejections and/or objections are either reiterated from the previous office action dated 7/9/2008 or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. The newly applied rejections are necessitated by the addition of claims 93-96.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

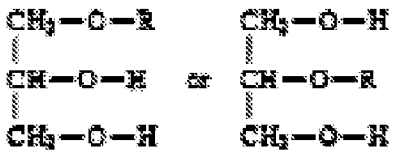
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 64, 66-67, 69-76, and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Traupe et al. (US 5,759,584) in view of Shalita et al. ("Topical Nicotinamide Compared with Clindamycin Gel in the Treatment of Inflammatory Acne Vulgaris" *Int. J. Derm.,* Vol. 4, No. 6, June 1995, pgs 434-437).

The instant claims are directed to composition comprising a combination of 1-glyceryl monocaprylate and niacinamide. It is noted that niacinamide is also known as nicotinamide (see page 3, line 5 of the instant specification).

Traupe et al. teach the use of a composition comprising distilled wool wax acids and at least one monoglycerol monocarboxylic acid monoester, or formulations comprising such active compound combinations for the treatment of blemished skin, mild forms of acne, and Propionibacterium acnes (see abstract and column 1, lines 29-41). Traupe et al. further teach that the monoglycerol monocarboxylic acid monoesters are represented by the general formula:



wherein R is particularly advantageously the octanoyl radical (caprylic acid radical), and in a preferred embodiment is glycerol monocaprylate (see column 3, lines 16-50 and column 4, lines 29-36). The glycerol ester esterified at the 1-position of glycerol (i.e. 1-glycerol monocaprylate) has a centre of asymmetry, wherein the 2S and 2R configurations are both active, and racemic mixtures of the stereoisomers is favorable as claimed in the instant claim 72 (see column 3, lines 48-56). Traupe et al. further teach that the formulations which are active against blemished skin can be in the form of face lotions, etc. indicating they include cosmetics formulated for topical administration (see column 4, line 55 to column 5, line 12).

Traupe et al. do not teach compositions additionally comprising niacinamide.

Shalita et al. teach 4% nicotinamide (niacinamide) gel is comparable in efficacy to 1% clindamycin gel in the treatment of acne vulgaris (see abstract). Shalita et al. further teach that the nicotinamide gel is a desirable alternative treatment for acne vulgaris because antimicrobials such as clindamycin are associated with resistant microorganism such as Propionibacterium (see abstract and page 434, and Discussion on pages 436-437).

It would have been obvious to one of ordinary in the art at the time of the invention to combine the wool wax and acid and glycerol monocaprylate composition taught by Traupe et al. with the nicotinamide composition taught by Shalita et al. One of ordinary skill in the art would have been motivated to so because both compositions

are useful for treating acne. One of ordinary skill in the art would have a reasonable expectation of success because both compositions are taught to target a specific cause of acne, namely Propionibacterium. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, it would be obvious to one of ordinary skill in the art at the time of the invention to optimize the ratio of 1-glycerol monocaprylate to niacinamide as claimed in the instant claims 71 and 93-96. Proportions of ingredients, to impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. *In re Fields* (CCPA 162) 304 F2d 691,134 USPQ 424.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617